UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,368	11/03/2003	Joseph M. Pastore	279.632US1	5953

21186 7590 10/31/2007

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	**PAPER NUMBER**
3762	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,368	PASTORE ET AL.	
	Examiner	Art Unit	
	Christopher A. Flory	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1 and 11 as being rejected under 35 U.S.C. §112, first paragraph have been considered but are moot in view of the amendments to the claims canceling the objected to subject matter (simultaneous atrial pacing). For the sake of clarification, the Examiner agrees that the disclosure supports delivery of parasympathetic stimulation in conjunction with multi-site ventricular stimulation (see Remarks, page 6, lines 7-9). Examiner further agrees that the disclosure supports certain embodiments including atrial pacing alone or in conjunction with multi-site ventricular pacing, but maintains the argument that the disclosure does not support an embodiment delivering atrial pacing *simultaneously* with parasympathetic stimulation and multi-site ventricular pacing. For example, page 8 lines 4-8 as referenced by the Applicant do show disclosure of atrial pacing in combination with biventricular resynchronization, but fails to meet the limitation of a simultaneous delivery. In resynchronization of the *ventricles* it is the *ventricles* that are paced simultaneously. The quoted section of page 10, line 28 through page 11, line 3 similarly fails to meet the limitation of simultaneous delivery. Additional support for this assertion can be found on page 7, lines 28-30: "The device is equipped with multiple sensing and pacing channels which may be physically configured to sense and/or pace multiple sites in the atria **or** the ventricles."

2. Applicant's arguments, see page 7, paragraph 3, filed 4 September 2007, with respect to the rejection(s) of claim(s) 1 and 11 under 35 U.S.C. §102(e) as anticipated

by Adams et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a different interpretation of the previously applied reference.

3. Applicant's arguments filed 4 September have been fully considered but they are not persuasive. Claims 1, 2, 4, 5, 7, 8, 10-12, 14, 15, 17, 18 and 20 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Casavant et al. (US 2004/0088015). Claims 1-3, 5, 7, 8, 10-13, 15, 17, 18 and 20 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Shafer et al. (US 2004/0172075).

Regarding Applicant's arguments directed to Casavant et al (see page 8, paragraph 1), Examiner maintains that a device configured for delivering parasympathetic stimulation in conjunction with multi-site ventricular pacing is disclosed in paragraph [35], with additional support for this disclosure being found in the abstract as well as paragraphs [5], [7], [10], [48], [51], [66], [68] and [75] of Casavant et al.

Regarding Applicant's arguments directed towards Shafer et al. (see page 8, paragraph 2), it is noted that although the '075 reference was filed on December 16, 2003, it nonetheless receives the priority to each of its parents for those limitations concerned with the instantly claimed invention, and therefore does qualify as prior art under §102(e)

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 4, 5, 7, 8, 10-12, 14, 15, 17, 18 and 20 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Casavant et al. (US 2004/0088015).

Applicant is directed particularly to the abstract as well as paragraphs [5], [7], [10], [35], [36], [48], [51], [60], [66], [68], [71] and [75], as well as Figs. 3-5.

6. Claims 1-3, 5, 7, 8, 10-13, 15, 17, 18 and 20 stand rejected under 35 U.S.C. 102(e) as being clearly anticipated by Shafer et al. (US 2004/0172075).

Applicant is directed particularly to paragraphs [23], [27], [28], [41] and [46], as well as Figure 5. Support for a demand pacing mode can be found in paragraph [60]. Further support that Shafer et al. discloses the multi-site ventricular demand pacing mode to prevent slowing of the heart rate due to the parasympathetic stimulation can be seen in Figure 5, as well as the disclosure of bradycardia treating embodiments in paragraphs [74] and [90].

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (U.S. 2003/0229380) in view of Gross et al. (US 2003/0045909).

In regards to claim 1, Adams et al. discloses an implantable device and method for delivering cardiac function therapy to a patient with multiple electrodes (see for example paragraphs 2, 9 and 12), in which includes and an embodiment comprising a biventricular pacing system (see for example paragraph 55), which is interpreted by Examiner to inherently include multiple pacing channels since the system comprises pacing at multiple sites. Adams et al. also discloses that the device comprises a parasympathetic stimulation system (see for example paragraph 11), which Examiner interprets as including a parasympathetic stimulation channel.

Further regarding claim 1, in the same field of endeavor, Lovett et al. (US 2002/0091415) discloses that ventricular wall stress and heart rate share an inverse relation, in that an increase of heart rate causes a decrease in pulse pressure and concomitantly a decrease in wall stress (paragraph [72]). Therefore, a therapy modality as described in Adams et al. which increases heart rate (ABSTRACT; paragraphs [5], [6]) also inherently decreases wall stress. Alternatively, Adams et al. teaches of a controller for controlling the delivery of pacing pulses to pacing sites (see for example paragraph 10), in which the controller can deliver pacing therapy in conjunction with parasympathetic stimulation (see for example paragraph 11), which Examiner interprets to be capable of reducing ventricular wall stress given that the Adams et al. device meets all the structural limitations set forth in the instant claims.

Still further regarding claim 1, Adams et al. is held to disclose a device capable of delivering stimulation simultaneously, as it meets all of the structural limitations set forth in the claims of the instant application.

Still further regarding claim 1, Adams et al discloses the invention substantially as claimed, but does not expressly disclose parasympathetic stimulation in conjunction with the ventricular pacing stimulation. However, in the same field of endeavor, Gross et al. teaches coupling a parasympathetic nerve stimulation device with an implanted deice for monitoring and correcting the heart rate, e.g. a bi-ventricular pacemaker, in order to increase the heart rate when heart rate is too low (paragraphs [9] and [193]). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Adams et al. with the combined stimulation as taught by Gross et al. to provide the Adams et al. invention with the same advantage of being able to selectively increase heart rate with an implanted pacemaker to compensate for a drop in heart rate caused by parasympathetic stimulation.

In regards to claim 2, Adams et al. discloses a sensor for measuring cardiac output (see for example paragraphs 10 and 92), wherein the controller is programmed to modulate the delivery of parasympathetic stimulation in accordance with the measured output (see for example paragraphs 11, 42 and 46).

In regards to claim 4, Adams et al. discloses slowing the heart rate of a patient by parasympathetic stimulation (see for example paragraphs 38 and 39).

In regards to claims 5, 7 and 8, Adams et al. discloses monitoring a patient's blood pressure, and the use of an activity sensor for monitoring a patient's exertion level (see for example paragraphs 46, 55 and 64).

In regards to claims 3 and 13, although Adams et al. teaches of the use of a sensor/circuit for measuring impedance to detect cardiac output (see for example paragraph 46), Adams et al. does not specifically teach of the use a trans-thoracic impedance measuring sensor/circuit. Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Adams et al. to include a trans-thoracic impedance to measure cardiac output, since this type of impedance sensor/circuit is well known in the art as a efficient and effective detector of cardiac output.

In regards to claims 6 and 16, Adams et al. teaches of the system providing parasympathetic stimulation when the activity level is below a particular value (see for example paragraph 46). Although Adams et al. does not specifically state that parasympathetic stimulation only when the measured activity level is below a particular value, Examiner takes the position that such a requirement would have been an obvious modification to one having ordinary skill in the art at the time of the invention since Adams et al. teaches that it is desirable to induce parasympathetic stimulation to reduce a patient's heart rate (see for example paragraph 11) when the activity level is stabilized (see for example paragraph 46), in order to provide effective and efficient parasympathetic stimulation.

In regards to claims 9, 10, 19 and 20, (see for example paragraphs 46 and 92), Adams et al. does not specifically state the use of a minute ventilation sensor or an accelerometer, for an exertion level sensor; however, Adams et al. does teach that the activity sensor can be one of a multiple types of exertion/metabolic level sensors (see for example paragraph 64). Thus, Examiner takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the system as taught by Adams et al. to include a minute ventilation sensor or accelerometer, since these are commonly known activity/exertion sensors that can be used to efficiently and effectively measure a patient's metabolic demand.

In regards to claim 11, Adams et al. discloses an implantable device and method for delivering cardiac function therapy to a patient with multiple electrodes (see for example paragraphs 2, 9 and 12), in which includes and an embodiment comprising a biventricular pacing system (see for example paragraph 55), which is interpreted by Examiner to inherently include multiple pacing channels since the system comprises pacing at multiple sites. Adams et al. also discloses that the device comprises a parasympathetic stimulation system (see for example paragraph 11), which Examiner interprets as including a parasympathetic stimulation channel.

Further regarding claim 11, in the same field of endeavor, Lovett et al. (US 2002/0091415) discloses that ventricular wall stress and heart rate share an inverse relation, in that an increase of heart rate causes a decrease in pulse pressure and concomitantly a decrease in wall stress (paragraph [72]). Therefore, a therapy modality as described in Adams et al. which increases heart rate (ABSTRACT; paragraphs [5], [6])

also inherently decreases wall stress. Alternatively, Adams et al. teaches of a controller for controlling the delivery of pacing pulses to pacing sites (see for example paragraph 10), in which the controller can deliver pacing therapy in conjunction with parasympathetic stimulation (see for example paragraph 11), which Examiner interprets to be capable of reducing ventricular wall stress given that the Adams et al. device meets all the structural limitations set forth in the instant claims.

Still further regarding claim 11, Adams et al. does not expressly disclose that the pacing is delivered simultaneously with the parasympathetic nerve stimulation. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to delivery the therapies in a synchronous manner, since synchronous pacing therapy as well as synchronous pacing and nerve stimulating therapies are well known in the implantable stimulator art.

In regards to claim 12, Adams et al. discloses a sensor for measuring cardiac output (see for example paragraphs 10 and 92), wherein the controller is programmed to modulate the delivery of parasympathetic stimulation in accordance with the measured output (see for example paragraphs 11, 42 and 46).

In regards to claim 14, Adams et al. discloses slowing the heart rate of a patient by parasympathetic stimulation (see for example paragraphs 38 and 39).

In regards to claims 15, 17 and 18, Adams et al. discloses monitoring a patient's blood pressure, and the use of an activity sensor for monitoring a patient's exertion level (see for example paragraphs 46, 55 and 64).

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

26 October 2007

/George Manuel/
Primary Examiner